

## **REMARKS**

### Claim Status

Claims 1, 3, 7-13, and 15-27 are pending in the present application. No additional claims fee is believed to be due.

Claims 1, 12, 13 and 27 are amended to further define wherein the composition comprises a zinc-containing layered material which is an impurity containing basic zinc carbonate. Support for the amendment is found in the specification at page 6, lines 5-7 -- The idealized stoichiometry is represented by  $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2$  but the actual stoichiometric ratios can vary slightly and other impurities may be incorporated in the crystal lattice. –

Claims 14-17 and 26 are canceled in view of the current amendments to Claim 1.

Claims 1, 3, 7-13 and 15-27 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claims 1, 9, 26 and 27 recite “greater than about” wherein the term ‘greater than’ provides a static point while the term ‘about’ provide a dynamic point which can be a little more or less than the value. Claims 1, 9-11 and 27 have been further amended by deleting the term “about”. Applicants respectfully request reconsideration and withdraw of the 35 U.S.C. 112, second paragraph rejection.

Claims 23-25 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in view that the claims merely recite a use without any active, positive steps delimiting how this use is actually practiced. Claims 23-25 have been further amended to comprise active, positive steps delimiting how the use is actually practiced. Support for this amendment is found in the specification at pages 32, line 20 to 33, line 32. Applicants respectfully request reconsideration and withdraw of the 35 U.S.C. 112, second paragraph rejection.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

**Rejection Under 35 USC §103(a) Over WO 01/00151 (hereinafter “Gavin et al.”) and WO 96/25913 (hereinafter “Bhat et al.”)**

Claims 1, 3, 7-13 and 15-27 have been rejected under 35 USC §103(a) as being unpatentable over WO 01/00151 (hereinafter “Gavin et al.”) and WO 96/25913 (hereinafter “Bhat et al.”).

The Office Action asserts that Gavin et al. do not expressly teach a composition comprising the zinc-containing layered material basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof. The Office Action further asserts that the deficiency in Gavin et al. is cured by the teachings of Bhat et al. It is further asserted that one of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition by not specifically basic zinc carbonate and Bhat et al. cures this deficiency by teaching the synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos. The Office action further asserts that the ‘zinc lability’ is an intrinsic property of the zinc salts since they are the same as instantly claimed. Applicants respectfully traverse this rejection.

Gavin et al. discloses a topical composition for the treatment of antimicrobial infections on the skin or scalp which includes a polyvalent metal salt of pyrithione, such as zinc pyrithione and a metal ion source. According to Gavin et al. the metal ion source can be a zinc salt. Suitable zinc salts are listed at page 7, first paragraph of Gavin et al. None of the zinc-containing layered materials as recited in claim 1 above or in currently amended Claim 1 are included in the list. In fact, Gavin et al. is completely silent as to the use of any of these zinc-containing layered materials for any purposes. In this regard, the Office Action cites Bhat et al. and asserts that one skilled in the art would add the zinc hydroxycarbonate disclosed in Bhat et al. to the composition disclosed in Gavin et al. to allegedly arrive at the claimed invention. Applicants respectfully traverse the rejections.

Bhat et al. in WO 96/25913 describes the preparation and use of a material termed “monophonic zinc hydroxycarbonate.” As described by Bhat et al., hydrozincite (naturally occurring) and basic zinc carbonate are equivalent names for zinc hydroxycarbonate (Page 1, lines 23-24 and line 35). The term “monophasic” is defined (Page 1, lines 29-33) as “without any other impurity phases ... present ...”.

The claimed invention, as now amended, requires from about 0.001 % to about 5 %, of a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate. Thus, the claimed invention, does not comprise a monophasic, or “without any other impurity phases” zinc hydroxycarbonate as defined by Bhat et al.

Applicants submit a Declaration under 37 CFR 1.132 from James R. Schwartz in support against the present Office Action assertions. Within the field of x-ray diffraction of crystal structures, “monophasic” means that only a single material is identifiable by its x-ray diffraction pattern. For example, a representative article in the field describes the synthesis of a monophasic solid  $\text{Ce}_{0.5}\text{Zr}_{0.5}\text{O}_2$  verified by observing only the peaks in the diffraction pattern associated with this material (J Mater Sci (2207) 42:3557-3563; Page 3560; attached with the 1.132 Declaration). When different preparative conditions are used, multiple phases are observed to be present in the diffraction spectra (Page 3561).

The 1.132 Declaration provides X-ray diffraction data generated for various sources of basic zinc carbonate materials. The most effective basic zinc carbonate materials of the claimed invention (e.g., from Bruggemann) are composed of *more than one phase* (i.e., is not monophasic, but is impurity containing) as evidenced by additional peaks (highlighted in yellow) beyond those that represent pure basic zinc carbonate, demonstrated below as Hydrozincite. (Table 1). When using X-ray diffraction to compare different commercial sources of basic zinc carbonate, i.e. Bruggemann, Elementis, and Cater, some appear primarily monophasic while others do not. While the sample in Table 2 from Bruggemann is multiphasic or impurity containing, as evidenced by additional peaks highlighted in yellow, the samples from Cater and Elementis show less evidence of this (noting also the broader peaks in the Bruggemann spectrum – another indication of multi-phasic nature).

Further, these difference of monophasic (without any other impurity phases ) vs. multi-phasic (impurity containing) are important to the behavior of basic zinc carbonate, as the higher purity materials (closer to monophasic) have lower relative zinc lability, as demonstrated in Table 3. This data demonstrates that Bruggemann-type basic zinc carbonate materials are not monophasic, and therefore, are impurity containing, and this is an important attribute of the claimed invention to achieve high performance. Thus, the Office Action assertion that Bhat et al. discloses the same formula for basic zinc carbonate as disclosed by Applicants and would intrinsically possess the same properties is incorrect. A monophasic basic zinc carbonate, such as those from Elementis and Cater, do not possess the same activity as a mutli-phasic or impurity containing basic zinc carbonate, as evidenced by the supporting data in the 1.132 Declaration.

From Table 3 in the 1.132 Declaration, the larger the FWHM, the smaller the crystallite size, the greater the crystalline imperfection and the lower the crystallinity. Thus, the crystallinity is in the order: Bruggemann < Elementis < Cater. The zinc lability increases as the crystallinity decreases, suggesting lower crystallinity (or smaller crystallite size) is more preferable to maximize zinc lability.

Such a difference of monophasic vs. multi-phasic or impurity containing are important to the behavior of basic zinc carbonate, as the higher purity materials (closer to monophasic) have lower relative zinc lability, as demonstrated in Table 3. In Table 3, Bruggemann, an impurity containing zinc-containing layered material, has a crystallite size of 103 Å and a relative zinc lability of 56.9%. Bruggemann comprises the smallest crystallite size and the largest relative zinc lability, when compared to Elementis and Cater. This data demonstrates that there is not only one measure, but rather *two* measures, crystallite size and relative zinc lability, that correlate with the one material in the table that is an impurity containing basic zinc carbonate, namely Bruggemann. Elementis and Cater, both monophasic and thereby fitting the description of Bhat et al, both contain *higher* crystallite sizes and *lower* relative zinc liabilities when compared to the impurity containing basic zinc carbonate of Bruggemann.

As described in the 1.132 Declaration and further in the specification at page 30, lines 11-15, zinc lability is a measure of the chemical availability of zinc ion. Of the three samples,

Bruggemann, the only impurity containing basic zinc carbonate, has the greatest availability of zinc ion with a relative zinc lability of 56.9%. The remaining two, Elementis and Cater, both have lower relative zinc labilities, 51.6% and 42.3% respectively, and thereby have decreased availability of zinc ions. And this is further paired with the fact that, as stated above, Bruggemann comprises the smallest crystallite size of 103 Å, as compared to Elementis and Cater, which have a crystallite size of 134 Å and 243 Å, respectively. The zinc lability of Bruggemann increases as the crystallinity decreases, suggesting lower crystallinity (or smaller crystallite size) is more preferable to maximize zinc lability, as demonstrated with Bruggemann.

There is no motivation to combine the teaching of Bhat et al. with Gavin et al. and arrive at the claimed invention, as neither Bhat et al. nor Gavin et al. disclose an impurity containing zinc-containing layered material which is an impurity containing basic zinc carbonate. Accordingly, the rejection is untenable and should be withdrawn.

### **Double Patenting**

1) & 2). Claims 1, 3, 4, 7-13, 15-17 and 23-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 8, 9, 11, 12, 14-17, 21 and 23-25 of copending U.S. Application No. 10/803,126. Claims 1, 3, 7-13, 15-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 8-12, 16-32 and 34-39 of copending Application No. 11/602,770. These 2 co-pending applications are jointly owned by The Procter & Gamble Company and Arch Chemicals, Inc. As all of the rejections are provisional, Applicants will respond if and when any allowable subject matter is identified. Therefore, Applicants requests that the provisional, obvious-type double patenting rejections be held in abeyance, until indication of allowable subject matter.

3) Claims 1, 3, 7-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 9, 13-30, 35 and 17 of copending Application No. 11/890,684.

Claim 1 of the Application 11/890,684 is directed to a composition comprising an effective amount of a particulate zinc material; an effective amount of a surfactant including a surfactant with an anionic functional group; an effective amount of a pyrithione or a polyvalent metal salt of a pyrithione; from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm; and from about 20% to about 95% of an aqueous carrier, by weight of said composition.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the impurity containing basic zinc carbonate has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to impurity containing basic zinc carbonate is greater than or equal to 2 to 1. Applicants point out that Claim 1 above, as now amended, is the same as Claim 26, now canceled. *Claim 26 has not been included in this obvious type double patenting rejection.*

The currently claimed invention is not directed to a composition containing from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm. Further, the '684 application is not directed to or requires a relative zinc lability of greater than about 15% for an impurity containing basic zinc carbonate. Yet further, the '684 application does not require the amount of zinc layered material a zinc-containing layered material *wherein the zinc-containing layered material is an impurity containing basic zinc carbonate and mixtures thereof or a ratio of surfactant to impurity containing basic zinc carbonate of greater than or equal to 2:1.* These 2 claim sets are patentably distinct and each of the specification and *data* demonstrate that the determination of liquid crystal phase in the '684 application or the ratio of surfactant to impurity containing basic zinc carbonate and relative zinc lability as required in the currently claimed invention are *not a matter of routine optimization.* In the '684 application, the surprising discovery that compositions combining

certain water soluble or dispersible, cationic, non crosslinked, deposition polymers in combination with surfactants form microscopically-phase separate lyotropic liquid crystals suspended in an aqueous surfactant phase is clearly patentably distinct. In use, the dispersed, concentrated polymer lyotropic liquid crystal phase provides improved hair and skin conditioning.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

4) Claims 1, 3, 7-13 and 15-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899,106.

Claim 1 of the Application 11/899,106 is directed to a composition comprising an effective amount of a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25°C; from about 5% to about 50% of a surfactant; and from about 40% to about 95% water; wherein the pH of the composition is greater than about 7.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrrhione or a polyvalent metal salt of a pyrrhione; wherein the impurity containing basic zinc carbonate has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to impurity containing basic zinc carbonate is greater than or equal to 2 to 1. Applicants point out that Claim 1 above, as now amended, is the same as Claim 26, now canceled. *Claim 26 has not been included in this obvious type double patenting rejection.*

The currently claimed invention is not directed to a composition comprising a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25°C. In contrast, the currently claimed invention requires the limitation of *a zinc-containing layered material wherein the zinc-containing layered material is an impurity*

*containing basic zinc carbonate.* Further, the '106 application claims require that the zinc containing material have an aqueous solubility within the composition of less than about 25% by weight at 25°C. The '106 application does not require a relative zinc lability of greater than about 15% for an impurity containing basic zinc carbonate, as required in the currently claimed invention. Yet further, the '106 application does not require the amount of *a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate* or a ratio of surfactant to impurity containing basic zinc carbonate of greater than or equal to 2:1. These two claim sets are patentably distinct.

These 2 claim sets are patentably distinct and the present specification and *data* demonstrate that the determination of the ratio of surfactant to impurity containing basic zinc carbonate as required in the currently claimed invention are *not a matter of routine optimization*.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

5) Claims 1, 3, 7-13, 15-22, 26 and 27 have been rejected on the ground of nonstatutory obvious-type double patenting over claims 1-5, 7, 8, 10-14, 17-21 of US Patent 7,026,308 in view of Bhat et al. (WO 96/25913).

In response to the above rejection, Applicants hereinwith submit a Terminal Disclaimer. Applicants respectfully believe that the Terminal Disclaimer serves to address this double patenting rejection. Accordingly, withdrawal of the double patenting rejection is respectfully requested.

#### Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 112 and 103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing,



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reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1, 3, 7-13, 18-25 and 27 is respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By /Linda Marie Sivik/

Signature

Linda M. Sivik

Typed or Printed Name

Registration No. 44,982

(513) 983-4639

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Customer No. 27752